

(b) As used in this section, the following terms shall have the meanings specified:

(1) The term *processed plant material* means cannabis plant material that has been subject to industrial processes, or mixed with other ingredients, such that it cannot readily be converted into any form that can be used for human consumption.

(2) The term *animal feed mixture* means sterilized cannabis seeds mixed with other ingredients (not derived from the cannabis plant) in a formulation that is designed, marketed, and distributed for animal consumption (and not for human consumption).

(3) The term *used for human consumption* means either:

(i) Ingested orally or

(ii) Applied by any means such that THC enters the human body.

(4) The term *intended for use for human consumption* means any of the following:

(i) Designed by the manufacturer for human consumption;

(ii) Marketed for human consumption; or

(iii) Distributed, exported, or imported, with the intent that it be used for human consumption.

(c) In any proceeding arising under the Act or this chapter, the burden of going forward with the evidence that a material, compound, mixture, or preparation containing THC is exempt from control pursuant to this section shall be upon the person claiming such exemption, as set forth in section 515(a)(1) of the Act (21 U.S.C. 885(a)(1)). In order to meet this burden with respect to a product or plant material that has not been expressly exempted from control by the Administrator pursuant to §1308.23, the person claiming the exemption must present rigorous scientific evidence, including well-documented scientific studies by experts trained and qualified to evaluate the effects of drugs on humans.

[66 FR 51544, Oct. 9, 2001]

HEARINGS

§ 1308.41 Hearings generally.

In any case where the Administrator shall hold a hearing on the issuance, amendment, or repeal of rules pursuant

to section 201 of the Act, the procedures for such hearing and accompanying proceedings shall be governed generally by the rulemaking procedures set forth in the Administrative Procedure Act (5 U.S.C. 551–559) and specifically by section 201 of the Act (21 U.S.C. 811), by §§1308.42–1308.51, and by §§1316.41–1316.67 of this chapter.

§ 1308.42 Purpose of hearing.

If requested by any interested person after proceedings are initiated pursuant to §1308.43, the Administrator shall hold a hearing for the purpose of receiving factual evidence and expert opinion regarding the issues involved in the issuance, amendment or repeal of a rule issuable pursuant to section 201(a) of the Act (21 U.S.C. 811(a)). Extensive argument should not be offered into evidence but rather presented in opening or closing statements of counsel or in memoranda or proposed findings of fact and conclusions of law. Additional information relating to hearings to include waivers or modification of rules, request for hearing, burden of proof, time and place, and final order are set forth in part 1316 of this chapter.

[62 FR 13968, Mar. 24, 1997]

§ 1308.43 Initiation of proceedings for rulemaking.

(a) Any interested person may submit a petition to initiate proceedings for the issuance, amendment, or repeal of any rule or regulation issuable pursuant to the provisions of section 201 of the Act.

(b) Petitions shall be submitted in quintuplicate to the Administrator in the following form:

(Date)
ADMINISTRATOR, DRUG ENFORCEMENT
ADMINISTRATION
Department of Justice,
Washington, DC 20537.

DEAR SIR: The undersigned _____ hereby petitions the Administrator to initiate proceedings for the issuance (amendment or repeal) of a rule or regulation pursuant to section 201 of the Controlled Substances Act.

Attached hereto and constituting a part of this petition are the following:

(A) The proposed rule in the form proposed by the petitioner. (If the petitioner seeks the

§ 1308.43

21 CFR Ch. II (4–1–02 Edition)

amendment or repeal of an existing rule, the existing rule, together with a reference to the section in the Code of Federal Regulations where it appears, should be included.)

(B) A statement of the grounds which the petitioner relies for the issuance (amendment or repeal) of the rule. (Such grounds shall include a reasonably concise statement of the facts relied upon by the petitioner, including a summary of any relevant medical or scientific evidence known to the petitioner.)

All notices to be sent regarding this petition should be addressed to:

(Name)

(Street Address)

(City and State)

Respectfully yours,

(Signature of petitioner)

(c) Within a reasonable period of time after the receipt of a petition, the Administrator shall notify the petitioner of his acceptance or nonacceptance of the petition, and if not accepted, the reason therefor. The Administrator need not accept a petition for filing if any of the requirements prescribed in paragraph (b) of this section is lacking or is not set forth so as to be readily understood. If the petitioner desires, he may amend the petition to meet the requirements of paragraph (b) of this section. If accepted for filing, a petition may be denied by the Administrator within a reasonable period of time thereafter if he finds the grounds upon which the petitioner relies are not sufficient to justify the initiation of proceedings.

(d) The Administrator shall, before initiating proceedings for the issuance, amendment, or repeal of any rule either to control a drug or other substance, or to transfer a drug or other substance from one schedule to another, or to remove a drug or other substance entirely from the schedules, and after gathering the necessary data, request from the Secretary a scientific and medical evaluation and the Secretary's recommendations as to wheth-

er such drug or other substance should be so controlled, transferred, or removed as a controlled substance. The recommendations of the Secretary to the Administrator shall be binding on the Administrator as to such scientific and medical matters, and if the Secretary recommends that a drug or other substance not be controlled, the Administrator shall not control that drug or other substance.

(e) If the Administrator determines that the scientific and medical evaluation and recommendations of the Secretary and all other relevant data constitute substantial evidence of potential for abuse such as to warrant control or additional control over the drug or other substance, or substantial evidence that the drug or other substances should be subjected to lesser control or removed entirely from the schedules, he shall initiate proceedings for control, transfer, or removal as the case may be.

(f) If and when the Administrator determines to initiate proceedings, he shall publish in the FEDERAL REGISTER general notice of any proposed rule making to issue, amend, or repeal any rule pursuant to section 201 of the Act. Such published notice shall include a statement of the time, place, and nature of any hearings on the proposal in the event a hearing is requested pursuant to §1308.44. Such hearings may not be commenced until after the expiration of at least 30 days from the date the general notice is published in the FEDERAL REGISTER. Such published notice shall also include a reference to the legal authority under which the rule is proposed, a statement of the proposed rule, and, in the discretion of the Administrator, a summary of the subjects and issues involved.

(g) The Administrator may permit any interested persons to file written comments on or objections to the proposal and shall designate in the notice of proposed rule making the time during which such filings may be made.

[38 FR 8254, Mar. 30, 1973. Redesignated at 38 FR 26609, Sept. 24, 1973, and further redesignated and amended at 62 FR 13968, Mar. 24, 1997]